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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,162	03/07/2002	Yoshihiro Sowa	14875-008001/C1-101PCT-US	4957

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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,162	SOWA ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

The Election filed on August 26, 2005 in response to the restriction requirement mailed June 28, 2005 is acknowledged and has been entered. Applicant's election of the invention of Group I with traverse is acknowledged. In view of the Applicant's arguments, the previous restriction requirement is hereby vacated and the following restriction is hereby imposed.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to GAL4, 9-in-part drawn to luciferase, 10-in-part drawn to luciferase, 11-17.

Group 2, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to GAL4, 9-in-part drawn to chloramphenicol acetyltransferase, 10-in-part drawn to chloramphenicol acetyltransferase, 11-17.

Group 3, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to GAL4, 9-in-part drawn to beta-galactosidase, 10-in-part drawn to beta-galactosidase, 11-17.

Group 4, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to GAL4, 9-in-part drawn to human growth hormone, 10-in-part drawn to human growth hormone, 11-17.

Group 5, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to GAL4, 9-in-part drawn to secreted alkaline phosphatase, 10-in-part drawn to secreted alkaline phosphatase, 11-17.

Group 6, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to LEXA, 9-in-part drawn to luciferase, 10-in-part drawn to luciferase, 11-17.

Group 7, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to LEXA, 9-in-part drawn to chloramphenicol acetyltransferase, 10-in-part drawn to chloramphenicol acetyltransferase, 11-17.

Group 8, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to LEXA, 9-in-part drawn to beta-galactosidase, 10-in-part drawn to beta-galactosidase, 11-17.

Group 9, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to LEXA, 9-in-part drawn to human growth hormone, 10-in-part drawn to human growth hormone, 11-17.

Group 10, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to LEXA, 9-in-part drawn to sectreted alkaline phosphatase, 10-in-part drawn to secreted alkaline phosphatase, 11-17.

Group 11, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to tetracycline repressor, 9-in-part drawn to luciferase, 10-in-part drawn to luciferase, 11-17.

Group 12, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to tetracycline repressor, 9-in-part drawn to chloramphenicol acetyltransferase, 10-in-part drawn to chloramphenicol acetyltransferase, 11-17.

Group 13, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to tetracycline repressor, 9-in-part drawn to beta-galactosidase, 10-in-part drawn to beta-galactosidase, 11-17.

Group 14, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to tetracycline repressor, 9-in-part drawn to human growth hormone, 10-in-part drawn to human growth hormone, 11-17.

Group 15, claims 6-in-part drawn to identification of an agent alone, 7, 8-in-part drawn to tetracycline repressor, 9-in-part drawn to sectreted alkaline phosphatase, 10-in-part drawn to secreted alkaline phosphatase, 11-17.

Group 16, Claims 6-in-part drawn to a method of identification of an agent and further comprising evaluating the selected test agent for anticancer activity, claim 18-in-part drawn to *in vitro* activity, claim 19.

Group 17, Claims 6-in-part drawn to a method of identification of an agent and further comprising evaluating the selected test agent for anticancer activity, claim 18-in-part drawn to *in vivo* activity, claim 20.

Group 18, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is GAL4 as claimed in claim 23, wherein the reporter gene encodes luciferase as claimed in claim 24.

Group 19, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is LexA as claimed in claim 23, wherein the reporter gene encodes luciferase as claimed in claim 24.

Group 20, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is tetracycline repressor as claimed in claim 23, wherein the reporter gene encodes luciferase as claimed in claim 24.

Group 21, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is GAL4 as claimed in claim 32, wherein the reporter gene encodes chloramphenicol acetyltransferase as claimed in claim 24.

Group 22, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is LexA as claimed in claim 32, wherein the reporter gene encodes chloramphenicol acetyltransferase as claimed in claim 24.

Group 23, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous

protein is tetracycline repressor as claimed in claim 32, wherein the reporter gene encodes chloramphenicol acetyltransferase as claimed in claim 24.

Group 24, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is GAL4 as claimed in claim 32, wherein the reporter gene encodes beta-galactosidase as claimed in claim 24.

Group 25, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is LexA as claimed in claim 32, wherein the reporter gene encodes beta-galactosidase as claimed in claim 24.

Group 26, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is tetracycline repressor as claimed in claim 32, wherein the reporter gene encodes beta-galactosidase as claimed in claim 24.

Group 27, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is GAL4 as claimed in claim 32, wherein the reporter gene encodes human growth hormone as claimed in claim 24.

Group 28, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is LexA as claimed in claim 32, wherein the reporter gene encodes human growth hormone as claimed in claim 24.

Group 29, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is tetracycline repressor as claimed in claim 32, wherein the reporter gene encodes human growth hormone as claimed in claim 24.

Group 30, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is GAL4 as claimed in claim 32, wherein the reporter gene encodes secreted alkaline phosphatase as claimed in claim 24.

Group 31, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous protein is LexA as claimed in claim 32, wherein the reporter gene encodes secreted alkaline phosphatase as claimed in claim 24.

Group 32, Claims 21, 22, 23-in-part, 24-in-part, drawn to an anticancer agent identified by the method of claim 6 as contemplated in the specification wherein the heterologous

protein is tetracycline repressor as claimed in claim 32, wherein the reporter gene encodes secreted alkaline phosphatase as claimed in claim 24.

The inventions listed as Groups 1-32 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups 1-32 appears to be a method of identifying an agent having cellular anti-proliferation activity using a two hybrid system wherein the system comprises Sp3 or a fragment thereof.

However, said technical feature does not constitute a special technical feature in view of Sowa et al. (Cancer Research 1999. 59:4266-4270). Sowa et al. teach the claimed two-hybrid assay system of Group 1.

Therefore, the technical feature linking the inventions of Groups 1-32 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups 1-32 are not so linked by the same or a corresponding special technical feature as to form a single general incentive concept and restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

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